Question Bank

(Biostatistics)

PHARMACOTHERAPY

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1. A study was conducted in America to find out the proportion of blacks and white Americans in California. This variable chosen is:

a. Nominal b. Ordinal c. Continuous d. Discreet numerical e. Dichotomous

Key: True: e

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2. The median of the following data, is: 1,2,4,6,8,10,11,13

a. 6 b. 8 c. 7 d. 10 e. 9 **Key: True: c**

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3. A household survey of 10 families was conducted by students of 4th year MBBS. In the collected data, the ages of heads of families were: 32, 34, 35, 36, 36, 42, 44, 46, 48, and 52. The mean age of heads of families is

a. 36 b. 38.5 c. 40 d. 40.5 e. 42 **Key: True: d**

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4. A nutritional research team followed serum levels of vitamin B12 in 120 children for three years to determine the association between cyanocobalamin deficiency and the subsequent risk of developing Megaloblastic anemia. The results were as follows:

VITAMIN B12 LEVELS Mean 260 pg/mL Median 226 pg/mL Mode 194 pg/mL

From the data, it can be concluded that this distribution is:

a. Normal b. Negatively c. Positively skewed d. Bimodal e. Multimodal

Key: True: c

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5. Serum cholesterol levels for two groups of Americans were recorded in 1989. The mean cholesterol levels of the two groups were compared. To determine whether the measurements were significantly different or not, the most appropriate statistical test would be:

a. Chi-square test b. Correlation analysis c. F test (ANOVA)

d. Student's t test e. Regression analysis **Key: True: d**

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6. In a descriptive study the mean is 220 and the standard error is 10, the 95 confidence limits would be:

a. 210 to 230 b. 215 to 225 c. 200 to 240 d. 220 to 230 e. 205 to 235

Key: True: c

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Biostatistics

7. For a survey, a village is divided into 5 lanes, each lane is sampled randomly. It is an example of:

a. Simple random sampling b. Standard random sampling
c. Systematic random sampling d. Cluster random sampling
e. Quasi random sampling **Key: True: d**

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8. The birth weights in a hospital are to be presented in a graph. This is best done by a:

a. Bar diagram b. Pie chart c. Histogram d. Pictogram e. Frequency chart

Key: True: c

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9. An analysis of the race of patients who visit an emergency room reveals that 40% are white, 25% are black, 20% are Native American, and 15% are Asian. These data would best be depicted graphically with a

a. Venn diagram b. Cumulative frequency graph c. Normal curve d. Histogram
e. Pie chart **Key: True: e**

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10. If six families were surveyed and the numbers of children per family were found to be 2, 3, 4, 4, 5, 6, fine the mean number of children per family

a. 2 b. 3.5 c. 4 d. 6 e. 4.5 **Key: True: c**

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11. If, in one of the groups of premature infants, the maximum value for hexosaminidase A was substituted with a much higher value. The value which is unlikely to be affected by this higher value is:

a.Variance b. Range c. Standard deviation d. Median e. Mean

Key: True: d

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12. In study carried out in the hospital ward, every 10th admitted patient was included in the sample, which sampling procedure is this:

a. Random sampling b. Stratified sampling c. Quota sampling
d. Convenient sampling e. Systematic sampling **Key: True: e**

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Biostatistics

13. Three groups of subjects were followed over the course of five years to compare treatments for sideroblastic anemia. The most appropriate statistical analysis to determine the quantitative serologic differences resulting from these treatments would be

a. Regression analysis b. F test (ANOVA) c. Correlation analysis

d. Chi-square test e. T test **Key: True: b**

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14. In a class of 134 medical students, the mean systolic blood pressure was found to be 126 mm Hg with a standard deviation of 6 mm Hg If the blood pressures in this sample are normally distributed, what portion of the medical students will have systolic blood pressures above 132 mm Hg?

a. 0.5% b. 2.5% c. 5% d. 16% e. 32% **Key: True: d**

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16. Malaria cases were reported throughout the world during the year 1971 – 1978 excluding African region. These cases can be best represented by:

a. Frequency polygon b. Histogram c. Line diagram d. Pictogram

e. Scatter diagram **Key: True: c**

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17. There are 50 individual in population and they have same hemoglobin level that is 14g/dL. As there is no variability, the standard deviation will be:

a. 0 b. 1, -1 c. 0, 1 d. +2 e. -2 **Key: True: a**

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18. A mean hemoglobin level of 100 women in a population sample is 12g/dL with standard deviation of 0.2 The confidence interval for the population mean would be:

a. 10.4 – 11.6 b. 11.6 – 12.4 c. 12.4 – 13.6 d. 13.6 – 14.4 e. 14.4 – 15.6

Key: True: b

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19. The students of4th year MBBS class visited a school. The numbers of students per class from class I to class IX were as follows: 27, 23, 15, 18, 30, 24, 8, 12 and 16. The median number in this series is:

a. 12 b. 15 c. 16 d. 18 e. 23 **Key: True: d**

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Biostatistics

20. In a village of 300 population, 60% constitute Hindus, 20% Muslims, 10% Sikhs and 10% Christians. We want to take a sample of 10% of the population to study the eating habits of this population. The best method would be:

a. Simple random sampling b. Stratified random sampling
c. Systematic random sampling d. Non-random sampling
e. Cluster sampling **Key: True: b**

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21. The median of a series of 20 observations is 10, mean is 11.5 and mode is 11, which of the following measures can be subjected to statistical manipulation:

a. Sample size b. Mean c. Median d. Mode e. Range **Key: True: b**

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22. Which of the following can have more than one value?

a. The mean b. The range c. The mode d. The median e. Standard deviation.

Key: True: c

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23. The distribution of heights of the girls was plotted. The most frequent value was 5' – 2", which gives a single most important clue to its:

a. Negative skewness b. Positive skewness c. Normal distribution
d. Large standard deviation e. Multi modal distribution **Key: True: c**

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24. A large study of bladder cancer and cigarette smoking produced the following data: INCIDENCE OF BLADDER CANCER (per 100,000 males per year) Cigarette smokers 48.0 Non-smokers 25.4.The relative risk of developing bladder cancers compared with non-smokers is:

a. Categorical variable b. Ordinal data
c. Numerical, continuous variable d. Numerical, discrete variable
e. Proportion **Key: True: c**

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25. Birth rates of a population of infants at 40 weeks gestational age are approximately normally distributed, with a mean of 3000 grams. Roughly 68% of such infants weigh between 2500 and 3500 at birth. If a sample of 100 infants was studied, the standard error would be

a. 50 b. 100 c. 200 d. 250 e. 500 **Key: True: a**

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Biostatistics

26. When the standard for accepting the difference was at P-value of 0.05 and the calculated value was 0.01, the null hypothesis was rejected by the researcher. What do you think of results?

a. Wrongly rejected b. Significant difference c. No difference
d. Alternate hypothesis is wrong e. Sample size was small **Key: True: b**

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27. A study was conducted to assess the heights of 30 students. By chance all of the students were found to be of the same height. The standard deviation of this study sample is:

a. Zero b. 0 –– -1 c. 0 –– +1 d. 0 –– +2 e. 0 –– -2 **Key: True: a**

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28. In the Medical OPD of teaching hospital. diastolic blood pressures of 10 patients were as follows: 80, 75, 81, 79, 71, 95, 75, 77, 84, & 90. The mean of this data is:

a. 80 b. 81 c. 82 d. 83 e. 84 **Key: True: b**

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29. A normal distribution curve is based mainly on:

a. Mean and sample size b. Mean and standard deviation
c. Range and sample size d. Range and standard deviation
e. Mean and range **Key: True: b**

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31. A study was conducted to assess the height of students of 4th year in 10 Medical colleges the values of heights ranged between 5.5 – 5.10 feet. A histogram has been selected by the researcher to present these results as it is a:

a. Nominal data b. Categorical data c. Both qualitative and quantitative data
d. Continuous data e. Discrete numerical data **Key: True: d**

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34. A study was conducted to assess the height of students of 4th year in 10 Medical colleges. The values of heights ranged between 5.5 – 5.10 feet. Which graph should be used by the researcher to present the obtained data?

a. Bar chart b. Histogram c. Pie chart d. Scatter diagram e. Line graph

Key: True: b

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35. The median of the following data, is: 1,2,4,6,8,10,11,13

a. 6 b. 8 c. 7 d. 10 e. 9 **Key: True: c**

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Biostatistics

36. A large study of bladder cancer and cigarette smoking produced the following data: INCIDENCE OF BLADDER CANCER (per 100,000 males per year) & Cigarette smokers 48.0 &Non-smokers 25.4 .The relative risk of developing bladder cancers compared with non-smokers is:

a. Categorical variable b. Ordinal data
c. Numerical, continuous variable d. Numerical, discrete variable
e. None of the above **Key: True: c**

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38. The median of the following data, is: 1, 2, 4, 6, 8, 10, 11, 13

a. 6 b. 8 c. 7 d. 10 e. 5 **Key: True: c**

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39. After arranging the data is ascending or descending order of magnitude, the value of middle observation:

a. Mean b. Mode c. Median d. Geometric mean e. Mean deviation **Key: True: c**

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40. The area between two standard deviations on either side of the mean (X + 2S.D) will include approximate how much values in the distribution?

a. 68% b. 95% c. 99.7% d. 100% e. 90% **Key: True: b**

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42. If the mean cholesterol value of a group of normal subjects is 230 mg% with a standard error of 20. The 95% confidence limit for the population is:

a. 220-240 b. 210-250 c. 200-260 d. 190-270 e. 180-280 **Key: True: d**

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43. Birth rates of a population of infants at 36 weeks gestational age are approximately normally distributed, with a mean of 2500 grams. Roughly 95% of such infants weigh between 1900 and 3100 grams at birth. If a sample of 225 infants was studied the standard error would be:

a. 10 b. 20 c. 30 d. 40 e. 50 **Key: True: b**

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45. The distribution of height of the girls in a University was plotted. The most frequent value was five feet and two inches, while mean height was five feet and eight inches. This show:

a. Negative skewness b. Positive skewness c. Normal distribution
d. Large standard deviation e. Multimodal distribution **Key: True: b**

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46. A household survey of 10 families was conducted by students of 4th year MBBS. In the data they collected, the ages of heads of families were: 32,32,36,48,34,46,35,44,36 and 32 years. The mode in this series:

a. 32 b. 34 c. 36 d. 44 e. 46 **Key: True: a**

Biostatistics

47. In the Medical OPD of teaching hospital, diastolic blood pressures of 10 patients were as follows: 80, 75, 81, 79, 71, 95, 75, 77, 84, & 90. The mean of this data is:

a. 80 b. 81 c. 82 d. 83 e. 84 **Key: True: b**

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48. An investigator gets a positively skewed data on account of having only a small number of simple numerical observations at extremely high values. It will give an over estimate of:

a. Mean b. Median c. Mode d. Correlation **Key: True: a**

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49. An investigator gets a positively skewed data on account of having only a small number of simple numerical observations at extremely high values. Which measure of central tendency should he select if data is numerical?

a. Mean b. Median c. Mode d. Geometric mean **Key: True: b**

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50. When a relationship between the heart rate and valsalva's ratio is studied, mean is useful but dispersion of the data is also very useful. Which method of spread will be more useful in this?

a. Range b. Standard deviation c. Coefficient of variance d. Percentage
e. Inter quatile range **Key: True: c**

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51. In a descriptive study the mean is 200 and the standard error is 5, the 95 confidence limits would be:

a. 180 to 200 b. 190 to 200 c. 180 to 210 d. 200 to 220 e. 190 to 210 **Key: e**

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52. An analysis of the race of patients who visit an emergency room reveals that 40% are white, 25% are black, 20% are Native American, and 15% are Asian. These data would best be depicted graphically with a

a. Venn diagram b. Cumulative frequency graph c. Normal curve
d. Histogram e. Pie chart **Key: True: e**

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53. An investigator gets a positively skewed data on account of having only a small number of simple numerical observations at extremely high values. It will give an over estimate of:

a. Mean b. Median c. Mode d. Correlation e. Modal class **Key a**

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54. In a household survey conducted on ten families the frequency of family members in different age groups was less than 5 years □ 21, 5 – 14 years □ 16, 15 – 64 years □ 77 &> 65 years □ 1. The relative frequency of members in 15 – 64 years age group would be:

a. 47% b. 57% c. 67% d. 77% e. 87% **Key: b**

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Biostatistics

55. At endocrinology unit, serum calcium levels of 200 patients of hyperparathyroidism were checked. The mean serum calcium level was 14mg/dl with a variance of 0.5. The 95%confidence interval would be:

a) 13.2-15.2 b) 13.5-14.5 c) 13.5-15.5 d) 13.7-14.3 e) 13.9-14.1 **Key: e**

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56. While entering the data into SPSS, the analyst assigned numbers from 1-5 to different skin colors; cyanotic-1, reddish-2, pallor-3, bluish purple-4, yellowish-5. This type of variable will be categorized as:

a) Nominal b) Ordinal c) Dichotomous d) Continuous e) Discrete **Key: a**

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57. The cardiologist expresses the amount of edema in CCF patients in terms of absent, mild, moderate and severe. The statistician will describe this data as:

a) Nominal b) Ordinal c) Dichotomous d) Continuous e) Discrete **key: b**

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58. Serum ALT levels of Hepatitis c positive patients taking interferon therapy were done repeatedly as a marker to see the effect of therapy. This variable chosen is:

a) Nominal b) Ordinal c) Discrete d) Continuous e) Dichotomous **Key: d**

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59. Chairman POF board has announced scholarships for the students of WMC achieving 1st,2nd and 3rd positions in UHS in their relevant professional exams. The data of position holder students is categorized as

a) Nominal b) Ordinal c) Discrete d) Continuous e) Dichotomous **Key: b**

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60. Birth record of obstetric ward of POF hospital for the month of July showed that 50 infants (underweight) = <2500gm 150infants (normal) = >2500gm<400gm 30infants (over weight) = >400gm.This type of data is categorized as

a) Nominal b) Ordinal c) Discrete d) Continuous e) Dichotomous **Key: c**

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61. The systolic blood pressures of 15 patients coming to a tertiary care hospital with stroke were recorded as follows 156,174,148,185,150,170,176,188,180,180,150,200,220,140 and 150 The mean of this data will be

a) 140 b) 156 c) 164 d) 171 e) 183 **Key: d**

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62. The data regarding the naturopathic complications of diabetes mellitus depending on the duration of illness was recorded in following 6 categories depending on the duration of illness with class interval of 5 class I = 1-5years, class II= 6-10 years, class III= 11-15years, Class IV = 16-20years Class V = 21-25years Class VI =>25 years. This data can be graphically represented by

a) Pie chart b) Histogram c) Bar diagram d) Scatter diagram e) Pictogram **Key: c**

Biostatistics

63. Birth weights of the babies of PIH patients were recorded to see the effect of PIH on fetal weight. The measures of the central tendency for the data obtained were as follows : Mean = 200gm & Median = 2500gm & Mode = 2800gm.If graphically represented this data will be

a) Normally distributed b) Negatively skewed c) Positively skewed d) Bimodal
e) Poly modal **Key: b**

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64. The blood urea levels of the renal failure patients were recorded. The highest level was 110mg/dl and the lowest level was 50mg/dl. The range of the values will be

a) 40 b) 55 c) 60 d) 75 e) 80 **Key: c**

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65. In a study on 100pregnant ladies to determine the average weight gain in pregnancy the mean of the sample was 14kg with a SD of 5kg.if the data is normally distributed the %age of the women that will have weight beyond the range of 4-24kg

a) 68% b) 34% c) 27% d) 13.5% e) 5% **Key: e**

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66. The data of a sample of 400 IHD patients with smoking for the last 10years was normally distributed around the mean with the SD of 8. The S.E would be

a) 0.2 b) 0.4 c) 0.8 d) 1.0 e) 1.4 **Key: b**

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67. In a study of a new drug for arrhythmia, a researcher wishes to compare average serum drug concentrations in volunteers, four hours after taking the drug; in the fasting state then after a meal which of the following would be the most appropriate statistical test to use?

A. chi-squared test B. Pearson's correlation coefficient C. Student's paired t-test
D. Student's unpaired t-test E. Wilcoxon test **Key: C**

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Biostatistics

68. In this scenario we are dealing with use of the drug in the same volunteers with the intervention being the effect of feeding on drug concentrations. Thus you'll be comparing means in the same subjects and the paired t-test would be the most appropriate test
In a trial of a new antihypertensive drug the following results were obtained:

	Improved	Not improved
Treatment group	**44**	**16**
Placebo group	**36**	**26**

Which of the following statements regarding the statistical analysis or interpretation of the trial is true?
A. A Student t-test could be used.
B. Pearson's coefficient of linear regression would be an appropriate significance test.
C. The data could be evaluated using the Chi-squared test.
D. The numbers are too small to draw any conclusions.
E. The results so obviously show the benefit of treatment that statistical analysis is not required

Answer: C
This data would be ideal for a Chi-squared test. It is a 2 x 2 contingency table for which there is a special Chi-squared formula that gives a value that can be looked up in a table giving the p value. Nothing is ever so obvious that no statistical analysis is needed surely? Pearson's coefficient cannot be calculated as there is no linear regression to plot. The Student t-test cannot be used as we are comparing proportions not means.
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69. In significance testing which of these statements is correct?
A. A Type I error is to reject the alternative hypothesis when it should be accepted.
B. A Type II error is to accept the alternative hypothesis when it should be rejected.
C. The probability associated with a Type I error is the significance level.
D. The significance level is determined at the end of a significance test.
E. The significance level is always set to 5%.
Answer: C
The null hypothesis is that there is no difference between two groups. The alternative hypothesis is that there is a difference.
Rejecting the null hypothesis when there really is no difference between the two groups is a Type 1 error.
Accepting the null hypothesis (rejecting the alternative hypothesis) when there is a difference is a type 2 error.
Rejection of the null hypothesis depends on the probability -significance level which is usually (but not always) at $p < 0.05$.

Biostatistics

70. In a study of cholesterol level in a specific ethnic population, the researcher is concerned that his spread of cholesterol level is larger than that described in the general population. Which of the following terms most appropriately describes the spread of cholesterol level ?

A. Mean B. Median C. Mode D. Standard deviation
E. Standard error of the mean

Answer: D

Standard deviation is a measure of the spread of observations about the mean. It is based of the deviation of each observation from the mean value. Each value is squared, summed and divided by the total number of observations less one. The standard deviation is the square root of this value.

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71. A study of patients with moderately severe persistent asthma reports the mean number of salbutamol puffs that were used over a 2-week period. In a sample of 100 patients the mean number of puffs used over the observation period was 26. The authors report a standard error of the mean (SEM) of 1. You would like to know about the variability of salbutamol usage in the sample. Which one of the following represents the value of the standard deviation (SD) that gives you such information?

A.1 B.10 C.100 D.260

Answer: B

The standard deviation and the standard error of the mean are related mathematically.
Usually the SEM is calculated from the SD and sample size, but, like any algebraic relationship, you can solve the equation for any of the variables when given the other two.
The SEM can be calculated by dividing the SD by the square root of the sample size.
As such the SD can be calculated by multiplying the SEM by the square root of the sample size.
In this case, the SEM (i.e., 1) times the square root of 100 (i.e., 10) equals 1 puff (answer a).

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Biostatistics

72. Admission to the hospital was also reported as an outcome in the study described in the above question. Which one of the following statistical tests would be most appropriate to discern any statistical differences in the proportion of patients being admitted to the hospital in the two groups?

A. ANOVA B. Wilcoxon signed rank C. Kruskal Wallis D. Fisher's exact test

Answer: D

The outcome "admission" is a dichotomous outcome as such it is analyzed with tests designed for nominal variables.

ANOVA (answer a) is used to compare 3 or more means calculated for continuous variables, **Wilcoxon signed rank and Kruskal Wallis (answers b and c)** are non-parametric tests used most commonly for ordinal variables.

Fisher's exact test (answer d) is the only test in this list used to analyze nominal variablesoxon signed rankC. Kruskal WallisD. Fisher's exact test

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73. In addition to these results, the authors also describe a "rule" to predict which patients in the study were finally admitted to the hospital based on their FEV1 at baseline, their change in FEV1 following the first dose of drug, their oxygen saturation at baseline, and their history of use of inhaled corticosteroids. Which one of the following is the appropriate statistical technique to derive such a proposed rule?

A. a correlation analysis **B. a survival analysis**

C. a regression analysis **D. an analysis of variance**

Answer: C

A regression analysis (answer c) is the type of analysis that is used to construct predictive models. Regression allows for different variables to be added or subtracted from a model to discern the best predictive equation.

Correlation analysis (answer a) only explains how a variable changes in association with another variable and does not allow the prediction of one variable based on the value of the other.

Survival analysis (answer b) helps us to understand the probability of experiencing an outcome through a period of time.

Analysis of variance (answer d) is a type of inferential statistical test and is not used to predict values of variables.

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Biostatistics

74. A randomized trial investigates the difference in the incidence symptomatic deep vein thrombosis (DVT) when using two different injectable anticoagulants. After studying 32 patients, the p value comparing the percentage of DVT in each group is calculated as 0.12. Which one of the following is an important consideration in order to apply the results of this trial correctly?

A. type I error **B. type II error** **C. confounding by indication** **D. interviewer bias**

Answer: B

Because this is a randomized trial, the risks of influencing the outcome due to **confounding by indication (answer c) or interviewer bias (answer d)** are minimized. Even if these were potential concerns (which they are generally not for prospective trials), their risks should be distributed equally in each group due to the randomization.

Type I error (answer a), by definition, is only a consideration if a statistically significant difference is found.

Type II error (answer b) is important to consider whenever a non-significant result is reported in a clinical trial. The small sample size in this trial highlights this as a consideration even further.

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75. A study reporting patient satisfaction with care provided in a medical center, participants were asked to rate their satisfaction with their medical care on a 0-5 scale (0 = not satisfied at all, 5 = completely satisfied). Which one of these measures is best to describe patients' response to this question?

A. Mean **B. Interquartile range** **C. Median** **D. Mode**

Answer: C

- **Answer C (median) is correct** because, the median is an estimate of the center of the distribution of responses and is not sensitive to extremes. The median is a measure of average that can be used for ordinal data.
- **Answer A (mean) is incorrect**, because when the responses are ordered, it cannot be assumed that the distance between values is uniform.
- **Answer B (interquartile range) is incorrect** because this measure reflects the distribution of the central 50% of the data.
- **Answer D (mode) is incorrect** because the mode is the most common value

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Biostatistics

76. You wish to describe the type of patients who use the anticoagulation monitoring services your department provides. The Pharmacy and Therapeutics Committee is interested in the age of the population served. Which one of the following pieces of information will be most useful to the committee members?

A. Standard error of the mean (SEM) **B.t-test** **C. Mean** **D. Chi-square test**

Answer: C

For describing data that are continuous, measures of central tendency, such as the mean **(Answer C),** give a good overall description of the data.
Using **the SEM (Answer A)** to describe the age of a group of patients is not a good choice because this statistic measures the variability associated with different samples and does not represent the age of patients using the anticoagulation services.
T-tests and chi-square tests are used not as descriptive statistics but as inferential statistics.

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77. In a randomized, controlled study of pre-emptive analgesia in patients who underwent radical prostatectomy surgery, functioning was statistically (a=0.05) and clinically significantly improved in men who received the experimental treatment compared with men who received usual care. Which one of the following can be said about the assessment of statistical significance in this case?

A. The p value was less than or equal to 0.05.
B. The p value is an absolute indicator of which treatment was better.
C. The assessment of statistical significance is independent of the significance level.
D. Statistical significance was more important than clinical significance

Answer: A

- **Answer A is correct** because a p value less than or equal to the prespecified$\alpha$is interpreted as statistically significant.
- **Answer B is incorrect** because the p value does not indicate which treatment was better.
- **Answer C is incorrect** because the assessment of statistical significance depends on the chosen significance level.
- **Answer D is incorrect** because statistical significance is not necessarily more important than clinical significance.

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Biostatistics

78. In a regression model, individuals with MI had an odds ratio (OR) of 1.5 (95% Cl, 1.2-2.0) compared with individuals without MI. Which one of the following is the best way to interpret these results?

A. Having MI increased the likelihood that the person experienced the outcome by 150%.

B. Having MI increased the likelihood that the person experienced the outcome by 20% to 100%.

C. Having MI decreased the likelihood that the person experienced the outcome by 150%.

D. The estimated OR did not reflect a statistically significant result

Answer: B

- **Answer B** (an OR of 1.5 with a 95% Cl that extends from 1.2 to 2.0) is the correct interpretation of this estimate because the data are consistent with ORs from 1.2 to 2.0, as shown in the Cl.
- An OR of 1.2 is interpreted as a 20% increase in the likelihood that exposed individuals had the outcome, whereas an OR of 2.0 is interpreted as a 100% increase in the likelihood that exposed individuals had the outcome compared with unexposed individuals.
- **Answer A** (OR of 1.5 = 150% increase in likelihood of the outcome) is incorrect because an OR of 1.5 is not interpreted as a 150% increase in the likelihood of the outcome.
- An OR of 2.5 would represent a 150% increase, or an increase of 2.5 times the baseline odds.
- **Answer C** (an OR greater than 1.0 represents a decrease in the likelihood of the outcome) is incorrect because ORs above 1.0 are interpreted as increases in the likelihood of experiencing the outcome.
- Odds ratios below 1.0 are interpreted as a decrease in the likelihood of experiencing the outcome.
- **Answer D** (the estimated OR did not reflect a statistically significant result) is incorrect because the Cl for the OR did not cross 1.0.

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Biostatistics

79. In a randomized, controlled trial, investigators assessed whether there were overall differences between two treatments. Ninety people completed the trial, divided equally between treatments. Of those who received drug A, 29 experienced the outcome, whereas of those who received drug B, 14 experienced the outcome. Which one of the following is the best estimate of the OR for this study comparing the experience of individuals who received drug A with those who received drug B?

A.4.0 **B.0.25** **C.1.1** **D.0.9**

Answer: A

Answer A (OR = 4.0) is correct because the OR is estimated by cross multiplying and dividing the observed number of events, which are the four data cells of the table, not using the row or column totals at all.
In this case, this calculation is od/bc = (29 x 31)/(16 x 14) = 4.01.
Answer B, Answer C, and Answer D are simply incorrect calculations.

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80. A trial (n=48) reports that the average dose of an intravenous analgesic drug needed to keep pain below a rating of 2 on a 10-point scale is 67 mg with a standard deviation (SD) of 17mg.You wish to calculate a Cl for this mean dose. Which one of the following is the SEM associated with this result?

A.0.35 B.1.39 C.2.45 D.6.93

Answer: C

The SEM calculated from a single sample is determined by dividing the standard deviation by the square root of the sample size. For this case, then, 17 is divided by 6.93 to get an SEM of 2.45 (Answer C).

The other answers simply represent various calculation errors: 0.35 (Answer A) is the standard deviation divided by the mean; 1.39 (Answer B) results from dividing the mean by the sample size; and 6.93 (Answer D) represents the result of dividing the sample size by the square root of the sample size.

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Biostatistics

81. Which one of the following statements is the best interpretation for an OR of 4.0?

A. The odds of having the outcome among individuals who received treatment A are 10% higher than the odds among individuals who received treatment B.

B. The odds of having the outcome are 75% lower in individuals who received treatment A than those in individuals who received treatment B.

C. The odds of having the outcome among individuals who received treatment B are 10% lower than the odds among individuals who received treatment A.

D. The odds of having the outcome are 400% higher among individuals who received treatment A than those among individuals who received treatment B.

Answer: D

- **Answer D is correct** because the OR is an estimate of the odds of the outcome in individuals in one treatment group compared with individuals who received the other treatment. This answer represents the correct interpretation of an OR of 4.0.
- **Answer A is incorrect** because an OR of 1.1 is consistent with 10% higher odds of having the outcome among individuals who received treatment A than the odds of the outcome in individuals who received treatment B.
- **Answer B is incorrect** because this answer is consistent with an OR of 0.25.
- **Answer C is incorrect** because this is consistent with an OR of 1.1.

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Biostatistics

82. In a double blind randomized, controlled trial examining the effects of antihypertensive drugs, investigators found that the OR for treatment with low-dose diuretics compared with B-blockers for cardiovascular disease events was 0.86 (95% Cl, 0.77-0.97). Which one of the following statements is the most appropriate interpretation of these findings?

A. Treatment of hypertension with low-dose diuretics was 14% more effective in preventing cardiovascular disease events than treatment with β-blockers.

B. Treatment of hypertension with β-blockers was 14% more effective in preventing cardiovascular disease events than treatment with low doses of diuretics.

C. The difference observed between treatment with β-blockers and low doses of diuretics was not statistically significant.

D. Treatment of hypertension with low doses of diuretics was from 3% to 23% more effective in preventing cardiovascular events than treatment with β-blockers.

Answer: D

- **Answer D is a correct** interpretation of the Cl, and it accounts for the plausible range of estimates that are consistent with the data and expressed in the Cl.
- **Answer A is not as correct** as Answer D because the former estimate does not account for the Cl.
- **Answer B is incorrect** because it represents an incorrect interpretation of the results. Specifically, this meta-analysis did not find that P-blockers were more effective than low-dose diuretics.
- **Answer C is incorrect** the difference observed between treatment with p-blockers and low doses of diuretics is, in fact, statistically significant, because the Cl for the OR does not cross 1.0.

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Biostatistics

83. A cohort study to determine an association between measles, mumps, and rubella vaccination and autism, reported that the relative risk (RR) of autistic disorder in the vaccinated group compared with the unvaccinated group as 0.92 (95% confidence interval [Cl], 0.65-1.07).Which one of the following p values is consistent with these reported findings?

A. Less than 0.05 B. Less than 0.01 C. Greater than 0.05 D. Greater than 0,10.

Answer: C

- Cohort studies usually report the results of the comparisons between cohorts as RRs. This ratio represents the risk associated with an exposure compared with no exposure (or another exposure).
- Together with an estimate of the RRs, authors also should report an associated Cl. If this Cl includes the value of 1 within its bounds, then the possibility that the RR is different from 1 (i.e., that the risks are the same) cannot be excluded.
- Because the 95% Cl in this question ranges from 0.65 to 1.07 and includes the value of 1, you can conclude that the RR estimate of 0.92 is not a statistically significant difference from equal risk (RR = 1, or the same risk in the numerator and denominator).
- A p-value of less than 0.05 or less than 0.01 **(Answer A and Answer B)** are counted as statistically significant. Because the Cl does not quantify the p value, it can only be said that it is not statistically significant.
- Although both a p value of greater than 0.05 or greater than 0.10 **(Answer C and Answer D)** represent non-significant results, readers are limited to concluding that the p value is greater than 0.05 **(Answer C)** on the basis of the Cl.

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Biostatistics

84. A trial compares drug X and drug Y for treating nausea and vomiting associated with pregnancy. Drug X has been used for many years and has a large evidence base showing efficacy and safety. Drug Y was recently introduced to treat nausea and vomiting associated with chemotherapy, but it has not been well studied in patients with nausea and vomiting caused by pregnancy. Patients will be randomized to one of these two drugs. Which one of the following represents the correct statement of the null hypothesis (HQ) for this trial?

A. The efficacy of drug X equals the efficacy of drug Y.
B. The efficacy of drug X does not equal the efficacy of drug Y.
C. The efficacy of drug X is greater than the efficacy of drug Y.
D. The efficacy of drug X is less than the efficacy of drug Y.

Answer: A

- For this type of comparison, the HQ posits no difference between groups **(Answer A)**. If the statistical comparison of the difference observed between groups is unlikely attributable to chance, then the HQ is rejected, and a statistically significant difference can be concluded. **Only Answer A reflects this definition.**
- **Answer** is the definition for the alternative hypothesis in this case.
- **Answer C and Answer D** also could be the H0if the alternative hypothesis in this case. **Answer C and Answer D** also could be the H0if the alternative hypothesis of interest were that drug X was more effective (Answer C) or that drug X was less effective (Answer D).
- prospective, randomized, double-blind study (n=2200) finds that when two oral drugs for treating type 2 diabetes mellitus are compared, the final mean percent hemoglobin A1C value is 8.21 for patients in group 1 and 8.27 for patients in group 2. This difference between the groups is stated as having a

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Biostatistics

85. A prospective, randomized, double-blind study (n=2200) finds that when two oral drugs for treating type 2 diabetes mellitus are compared, the final mean percent haemoglobin A1C value is 8.21 for patients in group 1 and 8.27 for patients in group 2. This difference between the groups is stated as having a calculated p value less than 0.05. Which one of the following statements best characterizes these findings?

A. The difference between the drugs is clinically but not statistically significant.
B. The difference between the drugs is both statistically and clinically significant.
C. The difference between the drugs is statistically, but not clinically significant.
D. The difference between the drugs is neither statistically nor clinically significant.

Answer: C

- Not all statistically significant results are clinically important.
- If a large enough sample is studied, statistically significant differences can be demonstrated for small changes. In this large study, a difference in haemoglobin A1C of 0.06% was found to be statistically significant.
- However, changes of this magnitude are seldom measured with such precision in clinical practice. Moreover, changes in this small range are not associated with clinically different outcomes.
- As such, **Answer C best** describes the appropriate interpretation of these results.
- The other answers mislabel the results either as not statistically significant **(Answer A and Answer D)** or as clinically significant **(Answer A and Answer B).**

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86. You want to compare the effect of long term use of a drug on patient weight. You compare results between groups of children ages 2—5, 6—10, 11—14, and 15-18 years. Which one of the following statistical tests is the most appropriate choice?
A. Kruskal-Wallis B. Chi-square C.ANOVA D. Paired t-test

Answer: C

- **Answer C** is correct because the ANOVA test is a generalization of the t-test for more than two groups. This study compares four age groups.
- **Answer A** is incorrect because the Kruskal-Wallis test is a nonparametric analog of the ANOVA procedure, which is used for an ordinal dependent variable.
- **Answer B** (chi-square) is incorrect because weight is measured on a continuous, not categorical, scale. Chi-square tests can only be used with categorical data.
- **Answer D** (paired t-test) is incorrect because this test is used for comparing data from just two groups when data are paired, as in a pre-post design. Neither of these conditions applies in this case.

Biostatistics

87. A case-control study is performed to judge whether an antiemetic drug is associated with an increased incidence of early miscarriage. The final analysis shows that the OR for miscarriage with drug exposure is 1.3 (95% Cl, 0.9-1.7).Which one of the following provides a correct description of these results?

A.This drug increases the risk of miscarriage by 70%.
B.This drug increases the risk of miscarriage by 30%.
C.This drug decreases the risk of miscarriage by 10%.
D.This drug is not associated with an increased risk of miscarriage

Answer: D

- For % increased risk of miscarriage **(Answer A)** is incorrect since it is consistent with the upper bound of the Cl, not the point estimate of the OR.
- T -point estimate of the OR is 1.3. It can be said, given this value, that the risk is increased by 30% **(Answer B).**
- A 10% decreased risk of miscarriage with this drug **(Answer C)** might result if the lower bound of the Cl were considered.
- However, in examining the 95% Cl reported with the OR, it is seen that an OR of 1 cannot be excluded as representing the real relative odds for the groups (i.e., the Cl range encompasses the value of 1). Therefore, the findings are not statistically significant **(Answer D).**
- In prospective trials using continuous variables, a Cl that includes 0 would be interpreted as no difference.

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88. If you are to design a study in which the expected prevalence of a drug effect is very low. To compare the experience of individuals who took the drug with that of individuals who did not. Which one of the following statistical tests is most appropriate to use?

A. Z-test B. Fisher exact test C. T-test D. Analysis of variance (ANOVA)

Answer: B

- **Answer B** is correct because the data are categorical, and the Fisher exact test is used when the expected value of at least one cell of a 2 x 2 table is less than 5.
- **Answer A** (z-test) is incorrect because this statistical test is used when the data are normally distributed, the variance is known, and the data are continuous, not categorical, as in this case.
- **Answer C** (t-test) is incorrect because this statistical test is used when data are continuous and are relatively normally distributed and when the variance is unknown.
- **Answer D** (ANOVA) is incorrect because this test is a generalization of the t-test for more than two groups.

Biostatistics

89. A study assessed the relationship between a set of clinical and demographic characteristics and pain in individuals at the end of life who received hospice care. Pain was assessed when the person began receiving hospice care and every few days. The outcome of interest was whether the patient had severe pain at his/her last observation. Which one of the following types of analysis would be best to use in this case?

A. Linear regression
B. Survival analysis
C. Logistic regression
D. Ordered logistic regression

Answer: C

- **Answer C** is correct. The outcome of interest was whether the patient had severe pain at his/her last observation.
- **Answer A** is incorrect because this technique is used when the outcome is measured on a continuous scale.
- **Answer B** is incorrect because this approach is used when the outcome of interest is time to an event and when the analyst wants to account for censoring.
- **Answer D** is incorrect because this type of model is a generalization of logistic regression that allows the outcome to have more than two ordered categories.

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90. In a study, the r2= 0.32 which one of the following interpretations best explains this figure?
A. The model explains 57% of the variation in the outcome.
B. No conclusions can be drawn because it is not apparent whether the estimated coefficients for each covariate were statistically significant.
C. About 32% of the variation in the outcome was explained by the independent variable(s).
D. The model explains 75% of the variation in the outcome.

Answer: C

- **Answer C is correct** because the r2is an estimate of the variability in the dependent variable that is explained by the independent variable(s).
- **Answer A is incorrect** because an r2of 0.57 would be needed for this statement to be true. In this case, r = 0.57, not r2.
- **Answer B is incorrect** because consideration of statistical significance and accounting for variability in the dependent variable is different issues, tested against different null hypotheses.
- **Answer D is incorrect** because the square root of the correlation coefficient (r) is not used as a measure of variability in the dependent variable.

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Biostatistics

91. A randomized, controlled trial assesses the effects of a treatment for SLE on functioning in three groups of adults. Investigator assesses global functioning with an ordered, Like rt-type scale. Which one of the following statistical tests is most appropriate to assess differences in functioning between the groups?

A. Kruskal-Wallis B. Multiple ANOVA C.ANOVA D. Analysis of covariance (ANCOVA)

Answer: A

- **Answer A (Kruskal-Wallis)** is correct because this is the nonparametric analog to the ANOVA test, and the outcome is ordinal.
- **Answer B (multiple ANOVA)** is incorrect because the multiple ANOVA is used for normally distributed data when there are more than two groups and for multiple outcomes.
- **Answer C** is incorrect because the ANOVA is used for normally distributed data when there are more than two groups.
- **Answer D** is incorrect because the ANCOVA procedure is used when data are normally distributed and many independent variables exist, some of which are measured on a continuous scale.

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Biostatistics

92. In a study to assess the risk of stroke, myocardial infarction, death in the first 30 days after carotid endarterectomy, individual received the experimental intervention had an event rate of 8.2 %, whereas the event rate among individuals in the control group w 3.7%. You have been asked to estimate how many people would need to be treated with this intervention for one person to experience the outcome. Which one of the following is the best interpretation of that information?

A.About 22 individuals would need to be treated with the experimental intervention for one person to be harmed by the intervention.

B.About 0.2 individuals would need to be treated with the experimental intervention for one person to benefit from the intervention.

C.About 12 individuals would need to be treated with the experimental intervention for one person to benefit from the intervention.

D.About 27 individuals would need to be treated with the experimental intervention for one person to be harmed by the intervention.

Answer: A

- **Answer A (22 individuals) is correct** because the outcome of interest is some harm, and is calculated as the inverse of the absolute risk increase. In this case, the absolute risk increase is calculated by subtracting the outcome rate in the control group (3.7%) from that in the intervention group (8.2%), giving a difference of 4.5%. Expressed as a decimal, that gives 0.045, and the inverse, or number needed to harm, is 22.2.
- **Answer B (0.2 individuals) is incorrect** because the absolute risk increase needs to be expressed in decimal terms before the inverse is taken.
- **Answer C (12 individuals) is incorrect** because this estimate is the inverse of the outcome rate in the intervention group.
- **Answer D (27 individuals) is incorrect** because this intervention is the inverse of the outcome rate in the group.

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Biostatistics

93. A study tests whether the use of a new drug adherence aid method has an effect on congestive heart failure exacerbations. Researchers want to evaluate the proportion of patients with an exacerbation of their congestive heart failure symptoms in a group of people who used the adherence aid compared with a group of people who did not. Which one of the following tests is best to assess whether the changes observed are statistically significant?

A. McNemar **B. Chi-square** **C. Two-sample t-test** **D. Mann-Whitney U-test**

Answer: B

- Comparing nominal data is done using certain statistical tests developed for this purpose. Having or not having an exacerbation is a dichotomous type of outcome that meets the definition of nominal data.
- In this case, to compare two groups of nominal data, a chi-square test (Answer B) would be chosen.
- The McNemar test (Answer A) serves a role in statistical analysis similar to the chi-square, but it is used for data that are paired or matched (i.e., non-independent observations).
- A two-sample t-test (Answer C) is a parametric test used to compare two groups whose outcomes were measured on a continuous scale.
- The Mann-Whitney U-test is a nonparametric test, but it is used for comparisons using ordinal data.

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Biostatistics

94. A trial compares drug X and drug V for treating nausea and vomiting associated with pregnancy. Drug X has been used for many years and has a large evidence base showing efficacy and safety. Drug Y was recently introduced to treat nausea and vomiting associated with chemotherapy, but it has not been well studied in patients with nausea and vomiting caused by pregnancy. Patients will be randomized to one of these two drugs. The end point for this trial will be based on patients' ranking of their nausea and vomiting 3 hours after taking the drug to which they have been assigned. Nausea and vomiting will be graded using the following scale: 0 = no nausea, 1 = mild nausea, 2 = moderate nausea, 3 = severe nausea, and 4 = vomiting. Which one of the following types of statistical tests is best suited to test for differences between these drugs?

A. Wilcoxonrank sum test **B. Wilcoxonsigned rank test**
C. Student t-test **D. Paired Student t-test**

Answer: A

- Patients in this trial will be randomized to different treatment groups and not crossed over to the other group. Thus, the trial design measures the effect of the two drugs in each separate group of participants.
- With this knowledge, it can be concluded that these represent independent samples. Nausea and vomiting are graded using a ranking of symptoms the data collected would be considered ordinal.
- Because the researchers are collecting data from two independent groups assessed on an ordinal scale, Table 3 in this chapter helps the reader deduce that an appropriate test is the nonparametric Wilcoxon rank sum test **(Answer A).**
- **The Student t-test (Answer C)** is the parametric equivalent of this test and is applied to continuous data.
- **The Wilcoxon signed rank test (Answer B) and the paired Student t-test (Answer D)** are both used for paired data.
- The former is used with ordinal data, and the latter is used with continuous data.

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Biostatistics

95. A new antipsychotic drug was compared with a previously available drug in a prospective, randomized, and blinded trial. This 12-mon trial measured the frequency of inpatient psychiatric admissions both treatment groups. At the end of the trial, 6% of the patients taking the new drug had an inpatient psychiatric admission compared with 11% of the patients taking the older drug (p=0.03). In presenting the results of this trial to members of the formulary committee with the health maintenance organization where you work, Which or of the following statements would provide the committee with the best information to use in deciding the formulary status of the new drug?

A. The new drug decreased psychiatric admissions by 45%.
B. The new drug decreased psychiatric admissions by 83%.
C. You would need to treat two patients with the new drug to avoid one admission.
D. You would need to treat 20 patients with the new drug to avoid one admission.

Answer: D

- This question addresses concerns about presenting data as either relative changes or absolute changes.
- Because relative changes give no indication of the baseline frequency of an outcome, they should not be used as the sole basis for clinical or drug policy decisions; therefore, **Answer A is incorrect.**
- This representation of differences in hospitalization rates is the relative change that occurred between the two groups. It is the result of dividing the observed difference in admissions (5%) by the baseline rate (11%).
- **Answer B** represents the miscalculation of the relative change where the difference in admissions was divided by the rate of admissions in the group receiving the new drug.
- **Answer C and Answer D** both come from attempts to calculate the number needed to treat from the absolute difference in events between the groups. The number needed to treat is the reciprocal of the absolute difference between groups.
- **Answer C** is a miscalculation of that value, resulting from a misplaced decimal when converting 5% to its decimal form (i.e., a conversion to 0.5 instead of 0.05).
- **Answer D** is the best answer and reports the correctly calculated number needed to treat of 20 patients to prevent one admission.

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Biostatistics

96. A linear relationship between the dosage of a new chemotherapeutic drug and pulmonary function is being investigated. Measurements of the forced expiratory volume in 1 second are collected as a measure of I unit and plotted against the corresponding dosage of drug each paved.one of the following is an appropriate statistical approach to , any correlation between drug dose and forced expiratory vol in 1 second?

A. Pearson product moment coefficient. **B. ANOVA**
C. Spearman rank correlation **D. ANCOVA**

Answer: A

- This question describes a correlation analysis for two variables. It asks how much of the change in forced expiratory volume in 1 second associated with the use of a certain chemotherapeutic drug can be explained by the dosage? To perform such an analysis, researchers must first determine the type of variables being used.
- Variables with different levels of measurement require different statistical tests to characterize any association between them.
- In this case, the variables of forced expiratory volume in 1 second and dosage are measured on continuous scales.
- **The Pearson product moment coefficient (Answer A)** is recommended for such a combination.
- T**he Spearman rank correlation (Answer C)** would be used when assessing a proposed correlation between ordinal variables.
- **An ANOVA and an ANCOVA (Answer B and Answer D)** represent inferential statistical tests used when comparing more than three groups measured using continuous variables.

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Biostatistics

97. The statistical test applied to the data studying the relationship between this drug and lung function reports an r = -0.46 (p<0.05). Which one of the following represents the best interpretation of these results?

A.Seven percent of the variation in forced expiratory volume in 1 second is associated with the dose of this drug.

B.Twenty-one percent of the variation in forced expiratory volume in 1 second is associated with the dose of this drug.

C.Forty-six percent of the variation in forced expiratory volume in 1 second is associated with the dose of this drug.

D.Ninety-two percent of the variation in forced expiratory volume in 1 second is associated with the dose of this drug.

Answer: B

- The p value reported with the r for this association shows that the association between the dosage of this drug and forced expiratory volume in 1 second is statistically different from no correlation (i.e., r=0).
- In determining? the amount of the change in forced expiratory volume in 1 second t explained by changes in dosage, r2needs to be calculated. In this case, r2equals 0.21 and can be interpreted to mean that 21% of the variation in forced expiratory volume in 1 second is associated with changes in the one of the drug (Answer B).
- The negative sign reported with r indicates t the relationship is an inverse one such that increasing dosages of drug are correlated with decreases in forced expiratory volume in 1 second. Therefore, **Answer B is correct.**
- **Answer A (7%) is incorrect** because it is the square root of r.
- **Answer C (46%) is incorrect** because it is simply the raw r value.
- **Answer D (92%) is incorrect** because instead of squaring r, it multiplies r by 2.

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Biostatistics

Mark With (T) or (F)

•Mean, mode, median & SD calculations are applicable for continuous data [T]

•Median can be used to describe the central tendency of nominal data [F]

•Mode is the only measure of variability that can be used to describe nominal data [F]

•SD & SEM can be used to measure the variability of ordinal data [F]

•Ordinal data can have normal distribution pattern (parametric) [F]

•Continuous data can have discrete distribution pattern (Non Parametric) [T]

•Mean and mode are approximately equal for continuous data with parametric distribution [T]

•Confidence intervals give us an idea of the magnitude of the difference between groups as well as the statistical significance [T]

6

•P values give us an idea of the magnitude of the difference between groups as well as the statistical significance [F]

• In the interpretation of a difference between tow variables a CI that includes zero can be interpreted as not statistically significant [T]

•In the interpretation of a difference between odds ratio or relative risk a CI that includes one can be interpreted as not statistically significant. [T]

•In the interpretation of a difference between tow variables a CI that includes one can be interpreted as not statistically significant [F]

•If Null Hypothesis H0 is "rejected" this means that there is no statistically significant difference between groups being compared [F]

•Significance level (α): is used to determine the level of acceptable error caused by a false positive [T]

•Fisher exact test is a specialized version of the chi-square test for small groups containing fewer than five predicted observations [T]

7

•Type I Error **α** is concluding that no difference exists when one truly does (not rejecting H0 when it should be rejected) F

•Type II Error **β** is concluding that no difference exists when one truly does (not rejecting H0 when it should be rejected)… T

•Correlation examines the strength of the association between two variable T

• Regression examines the ability of one or more variables to predict another variable… T

•The power calculation tells you the probability that you will not make a t type II error T

•P=0.01 means that there is a 1% chance that results are either due to chance or random error T

•Correlation Coefficient (r):The strength of the "relationship" between 2 variables T

•Regression analysis provide the "predictability" of one variable on another Variable T

•Correlation Coefficient (r) determines causality… F

• Confounding variable is a variable that affects the independent or dependent variable, altering the ability to determine the true effect on the measured outcome. These factors may hide or exaggerate a true association T

•Relative risk and odds ratios can give an idea about the magnitude of causality between a factor and an outcome… F

8

Biostat

From Oncology board

1. Which of the following best describes the p value?

A. Is the probability that the results are due to chance alone.
B. Defines the clinical significance of the study.
C. Estimates the probability of beta error.
D. Quantifies the variability of the data.
Answer is A

- Probability due to chance alone. While the p value represents this probability, it is also used to determine statistical significance.
- By custom, p values less than 0.05 are considered statistically significant, and the null hypothesis is rejected.
- The groups are declared different because the probability that the difference is due to chance alone is sufficiently low based on the predetermined level of significance, $p<0.05$.
- The p value then also represents the probability that we may have made a Type I error, also called alpha error, in our analysis, the probability that no difference exists and we made the wrong inference.
- While the variability is considered in the calculations for determining the p value, the p value does not quantify the variability of the data.

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Biostatistics

2. Which of the following best describes properties of confidence intervals?

A. Describe the variability in the sample.
B. Cannot be used in hypothesis testing.
C. Provide the same information as p values.
D. Are calculated based on the standard error of the mean.

Answer is D

- Confidence intervals are calculated based on the standard error of the mean (SEM).
- CI is interpreted in several ways.
- One way of stating this information is if we were to repeat this study 100 times, we are 95% confident that the results would fall in this range. (95% because this is a 95% confidence interval.
- Any percentage could be selected, but this is the one most commonly used.
- The CI provides inferences on the population as a whole.
- P values do not provide any information on the range of values.
- However, CI can be used in hypothesis testing. If the range reported does not include the value indicating no difference (in this case for a HR, 1.0 would indicate no difference between the groups), then the results are considered statistically significant.
- However in this instance, the HR on the primary outcome does include one, which means the groups are not statistically significant.
- This is an interesting example note the confidence interval on the osteonecrosis: it includes 1, but is statistically significant when you look at the p value.
- This is because this is a confidence interval around the cumulative incidence reported and not a HR, RR or OR.

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3. By presenting a hazard ratio, instead of a relative risk, which of the following statistical analyzes was most likely used?

A. ANOVA **B. Chi-square** **C. Survival analysis** **D. T-test**

The answer is C

- Using a Hazard ratio instead of a relative risk is using a weighted relative risk over time. It is considered the stronger analysis and provides more information. Graphically, it is presented in a Kaplan Meier curve.
- This methodology is called survival analysis. If the authors had just used a relative risk, then a Chi-squared would have been an appropriate statistical analysis.
- ANOVA would be used for continuous data when more than 2 groups were used. T-test would be used for continuous data when 2 groups are compared.

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Biostatistics

4. In concluding there were no differences between the groups, the authors are most likely to have made which statistical error in making this conclusion:

A. Type I **B. Type II** **C. Both a Type I and Type II** **D. Neither**

The answer is B

- In concluding there were no differences between the groups, the researchers would have made a type II error.
- This can be prevented by studying enough patients.
- In this case there was a relatively large sample size. In calculating the sample size for this study, the researchers estimated they would need 3300 patients total (so this was achieved) and would conduct a final analysis after 940 patients had events.
- This was estimated to provide an 80% power to detect a relative reduction of 17%. Since the study was being conducted over 5 years, they built in an interim analysis when half of the events occurred.
- At this time, the rate of events in both groups was lower than expected. They revised their statistical plan and built in a second interim analysis.
- After the second analysis, the study was stopped for lack of efficacy. This is especially important that they study enough patients in a study such as this by stopping the study early, it could be criticized that they didn't see a difference because they didn't study enough patients or study them long enough to detect a difference.
- By conducting the analyses that they did, they preserved the power of the study, yet didn't expose patients to any additional risk longer than necessary.

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Biostatistics

5. True or False: A "p-value" helps the investigator determine the degree of clinical significance found in the study?

True (12%) **False (88%)**

Answer: is correct! 88% of people got this question correct.

- This is a high-yield concept that you must know. A p-value NEVER EVER indicates clinical significance. If you ever see the words "clinically significant" or "clinical significance" anywhere in the answer choice for a question pertaining to the interpretation of a p-value it is absolutely wrong.
- This is the most common trick question as too many people think that p-values reflect clinical significance because they fail to understand this concept.
- A p-value ONLY helps you to know whether the results that were found in the study were due to random error or due to chance alone.
- To make sure this concept is driven home, a p-value = 0.004 is NOT more clinically significant or relevant than a p-value of 0.05. It only means that there is a 0.4% chance that the results you found in that study was either due to random error or chance.
- Therefore, the smaller the p-value the more likely the results are real.

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6. Which of the following key assumptions must be met for a student's t-test to be used?

Nominal data (8%) **Categorical data (3%)** **Ordinal data (5%)** **Continuous data (84%)**

Answer: Continuous data 84% of people got this question correct.

- Several general rules must be met before a student's t-test can be appropriately used.
- The first is having an adequate sample size (usually > 30-40 patients - depends on what you read).
- The second includes having data that is both continuous and following a normal distribution.
- If the data is skewed or has significant outliers then a Mann-Whitney U test should be done instead.

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Biostatistics

7. Which of the following best describes a 95% confidence interval?
1. The width of the confidence intervals is not dependent on the standard error of the mean (SEM) (2%) It provides you the predictive properties of a test (1%)
2. If you were to repeat the study under ideal conditions, you would be 95% confident that your result would fall within that confidence interval (88%)
3. It helps you to determine if your result was due to chance or random error (9%)

Correct Answer: 2
Comment:

- This is definitely a high-yield concept for your exam. You must understand how to interpret and what a 95% CI is actually telling you and be able to do so from a number of different angles. Do not take a board exam without understanding this concept.
- Another way to say the same thing is, "you are 95% confident that the true population mean will fall within the confidence interval found from the experimental study group examined in the study."
- The wider the confidence interval the more likely that the "true" population value will be anywhere within that interval. Unfortunately, a wide confidence interval may indicate a problem with the study or data obtained.
- If you want to be sure that the true population mean is similar to the experimental mean obtained from the study, having a narrow or tight confidence interval would be ideal.

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8. One of the main reasons for a wide confidence interval is insufficient sample size.
A simple linear regression can be utilized to predict the outcome of the following:
There is a single independent and single dependent variable (77%)
There is more than one independent and only one dependent variable (7%)
There is a single dichotomous independent variable (5%)
There are two unrelated independent variables (10%)

Answer is correct! 77% of people got this question correct.

- Regression analysis is a mathematic description or equation that provides the "predictability" of one variable on another variable.
- For simple linear regression analysis, this is usually analyzes the relationship of two variables (1 being an independent variable and the other being a dependent variable).

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Biostatistics

9. When examining a set of data that used a continuous variable you find that the mean, median, and mode are approximately equal. In that case you expect that the data is more likely to be:

Parametric (92%) **Nonparametric (4%)** **Neither (4%)**

Answer is correct! 92% of people got this question correct.

Comment:

- An important key word is used in the question - "continuous variable". A continuous variable that generates data where the mean, median, and mode are very similar or equal, means that it follows a normal distribution or is homogenous.
- As such, it would be considered to follow the rules of being parametric where parametric statistical analysis would be used.
- It is important to note that "ordinal" data does not have a mean, but instead a median and mode and that "nominal" or "categorical" data generates only a mode.
- Knowing this can help you also narrow down on the question's answer.

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10. A scatter plot (used for determining a correlation coefficient) depicts the relationship between a dependent and independent variable and is used to determine:

Clinical significance (2%) **Statistical significance (4%)**

Association (83%) **Predictability (11%)**

Correct Answer: Association 83% of people got this question correct.

- A correlation analysis generates a correlation coefficient (r), which can range from being -1 to +1.
- It is done to describe the strength of the "relationship" between 2 variables whereas regression analysis is done to provide the "predictability" of one variable on another variable.
- The closer to +1, the stronger the "correlation" or "relationship" between 2 variables.
- It is also important to know that correlation does NOT imply anything about causation, thus making this question false.
- Lastly, the correlation (r) does not have the ability to determine which of the two variables came first in existence to influence the other.

Biostatistics

11. A group of investigators have designed a study to determine if simvastatin (Zocor) was more effective than pravastatin (Pravachol) for the treatment high cholesterol. They designed the study, so that 1000 patients would be randomly assigned to one of 2 groups: Zocor 40 mg once daily or Pravachol 40 mg once daily. At baseline, patients had fasting lipid profile done and were assessed for myopathy (muscle aches/pain). These patients were then prospectively followed for 3 months. At 3 months the patients had a follow up visit where fasting lipid profiles and patient assessments on myopathy (none, mild, moderate, or severe pain) were completed.The primary endpoint was to determine the change in LDL-c (mg/dL) from baseline. The secondary endpoints included:
1-The proportion of patients achieving their LDL-c goals per guidelines;
2-The patients rating of myopathy.
Which of the following statistical tests should you use when analyzing secondary endpoint number 1 (the proportion of patients achieving their LDL-c goal)?
McNemar Test (8%) **Chi Square (69%)**
Wilcoxin Rank Sum (20%) **Sign Test (3%)**

Correct Answer: Chi Square 69% of people got this question correct.
- The best way to figure this is to do the following:
1. First ask, "How many groups (or samples) does this study have?" = 2
2. Second, "Are these two groups (or samples) related (i.e., same patient) or independent (i.e., not the same patients in both groups)? = Independent
3. Third, now determine the endpoint, "What is the endpoint?" Since this case is asking about the proportion of patients who achieved an LDL-c goal of < 100 mg/dL, then the investigators would be looking at this endpoint as a "yes" or "no" question
(i.e., the patient either achieved an LDl-c goal of less than 140 or they did not), thereby making it nominal data.
- Thus, a study using 2 independent groups evaluating a nominal data variable, the correct statistical test would be a Chi Square test.
- If the question had been for the primary endpoint, then the investigators would want to know the change in LDL-c or the amount of lowering in the LDL-c in mg/dL.
- This is a concentration and thus each mg/dL is the same in magnitude and thus considered to be continuous (note: the change can be to infinity, there is no ranking or scale here).
- It is always important to read the endpoint in question carefully to see the subtle difference in wording as it changes everything where the answer would have been student's t-test.
- Board exams like to do this so make sure you understand this concept.

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Biostatistics

12. When the data reveals a mean less than the median less than the mode it can be described as being?

Normally distributed (2%) **Skewed to the left (74%)**
Skewed to the right (20%) **Positively Skewed (4%)**

Correct Answer: Skewed to the left 74% of people
Comment:

- Being "skewed to the left" is the same as saying the data is "negatively skewed". To clarify further, when they say skewed to the left, this means the mean is less than the median and/or the tail of the curve is on the left side of the graph.
- Thus, the opposite is true, if the data is skewed to the right the data is called positively skewed. Here the mean is now greater than the median (acting is an outlier) and thus skews the data to the right (note the tail of the curve is on the right of the graph)
- You should be able to quickly look at a graph like this and be able to interpret it any of the above explanations (or listed answer choices).

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13. A study of a randomized parallel design allocating patients (n=100) to either enalapril or quinapril, and evaluating their effects on plasminogen activating inhibitor (PAI)-1 production (measured as ng/ml). Which statistical test should be utilized?

Sign Test (2%) **Paired t-test (17%)**
Student's t-test (69%) **Chi square (12%)**

Correct Answer: Student's t-test 69% of people got this question correct.
Comment:

- The question describes a typical randomized, clinical trial where patients are randomly assigned to one of two groups.
- Since they never say the patients cross over in the study to other intervention, you must assume that they do not and thus are 2 independent groups (i.e., the patients in each group or intervention are not the same people - they are independent of each other).
- The dependent variable in question here is the effect on "PAI-1" production in a concentration of ng/ml.
- As such they are treating this data variable as "continuous data" where the magnitude of difference between each ng/ml is exactly the same and can on for infinity (for example, the difference between 20 and 21 ng/ml is 1 ng/ml and is the same as the difference between 45 ng/ml and 46 ng/ml; the magnitude of difference is always 1 and is not changing and it is "measurable" unlike with ordinal or nominal data).
- Therefore, with 2 independent groups analyzing continuous data, a student's t-test should be used.

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Biostatistics

14. Which of the following statistical test would be considered nonparametric?

1-way ANOVA (19%) **Student's t-test (6%)**
Fisher's Exact (71%) **Paired t-test (5%)**
Answer: is correct! 71% of people got this question correct.
Comment:

- All of the other statistical test involves the use of continuous data which is considered to be parametric data.
- You have to assume the data meets all of the rules to be parametric unless the question tells you something different.
- The rows from the table for nominal and ordinal data types are considered to be nonparametric because that data does not follow a normal distribution or is not normally distributed.
- As such, the Fisher's exact test utilizes nominal data sets and thus is a nonparametric test.

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15. A correlation between two variables implies that the dependent variable is the cause for the observed change?
True (28%) **False (72%)**
Correct Answer: False 72% of people got this question correct.
Comment:

- A correlation analysis generates a correlation coefficient(r), which can range from being (-1 to +1).
- It is done to describe the strength of the "relationship" between 2 variables whereas regression analysis is done to provide the "predictability" of one variable on another variable.
- The closer to +1, the stronger the "correlation" or "relationship" between 2 variables.
- It is also important to know that correlation does NOT imply anything about causation, thus making this question false.
- Lastly, the correlation (r) does not have the ability to determine which of the two variables came first in existence to influence the other.

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Biostatistics

16. A p value of 0.001 is more _____ significant than a p-value of 0.01?
Statistically (37%) **Clinically (2%)** **Neither a or b (61%)**

Answer: Neither a or b 61%.
Comment:

- This is a high-yield concept that you must know. A p-value NEVER EVER indicates clinical significance.
- If you ever see the words "clinically significant" or "clinical significance" anywhere in the answer choice for a question pertaining to the interpretation of a p-value it is absolutely wrong.
- This is the most common trick question as too many people think that p-values reflect clinical significance because they fail to understand this concept.
- A p-value ONLY helps you to know whether the results that were found in the study were due to random error or due to chance alone.
- You cannot even determine that one result or more statistically significant than another thus making answer (a) wrong as well - it simply tells you the likelihood of whether your results are due to random error or chance.
- Having a smaller p-value simply means the results that generated that lower p-value are less likely due to random error or chance.
- This seems like a trick question, but that has to do with the inappropriate use of words or terms by people.

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Biostatistics

Questions from NAPLEX

1. Which measure(s) of central tendency is/are sensitive to outliers?
(A) Mean (B) Median (C) Mode
Answer is A

- Mean is the correct answer because it is affected by outliers. Median and mode are incorrect because they are not affected by outliers.

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2. For what type of data can standard deviation (SD) be used?
(A) Parametric data (B) Ordinal data (C) Nominal data
Answer is A

- Parametric (aka continuous) data is correct. Standard deviation is only meaningful for parametric data.
- It is not meaningful for nominal data. Measures of variability are not meaningful for nominal data. Standard deviation is usually not meaningful for ordinal data. Interquartile range is the preferred measure of variability for ordinal data.

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3. Which of the following is correct regarding measures of variability?

(A) Range can be both descriptive and inferential.
(B) Standard error of the mean (SEM) is always larger than SD.
(C) All values contained in a confidence interval (CI) are statistically possible.
(D) CI is a descriptive measure only.
Answer is C

- **Answer C is correct** because all values within a CI are statistically possible.
- **Answer A is incorrect** because range is descriptive only. Range is not inferential because one is unable to "infer" statistical significance for a data set based on range.
- **Answer B is incorrect** because SEM is always smaller than SD.
- **Answer D is incorrect** because CI is not only descriptive but also inferential since one is able to "infer" statistical significance for a data set based on CI.

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Biostatistics

4. A study was performed to determine the effect of a new antipsychotic agent (Drug A) on psychosis in patients with underlying schizophrenia as compared to placebo. A sample size of 300 patients was calculated to be needed based on an alpha of 0.05 and beta of 0.2. The double-blind, parallel, superiority trial was performed in 350 patients for 8 weeks. At the end of the 8-week period, the new antipsychotic agent was found to induce remission in 20% of patients as compared to 19% in the placebo group (P = 0.04). Which of the following statements is true based on the results of the study?

(A) Drug A was found to have a statistically significant and clinically significant difference on remission of psychosis as compared to placebo.

(B) Drug A was found to have a statistically significant difference but not a clinically significant difference on remission of psychosis as compared to placebo.

(C) Drug A was found to have a clinically significant difference but not a statistically significant difference on remission of psychosis as compared to placebo.

(D) Drug A was not found to have a clinically or statistically significant difference on remission of psychosis as compared to placebo

Answer is B

- Answer B is correct. The difference was statistically significant because the P value was .04. Based on this P value, there is a 4% chance that a type 1 error occurred, which is less than the prespecified acceptable risk of 5% (present alpha was 0.05 or 5%).
- However, the difference was not clinically meaningful because there was only a 1% difference in the primary end point (induction of remission) between the treatment groups.
- For these reasons, answers A, C, and D are incorrect.

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Biostatistics

(For the next two questions)

A study of the effects of bupropion (Zyban) versus nicotine gum (Nicorette) on the primary end point of change in the number of cigarettes smoked per day in a parallel, randomized trial. The investigators plan to include 450 subjects (150 in each arm) to reach statistical significance based on a of 0.2 and of 0.05.

5. Which of the following statistical tests would be the most appropriate? (Hint: assume no confounders)

(A) One-way ANOVA **(B) Chi-square (2)** **(C) Fisher exact test**
(D) Friedman test **(E) t test**

The answer is E

Answer E is correct because a t test is the test of choice for evaluating statistical differences in parametric data (change in the number of cigarettes smoked daily) when only two groups are being evaluated and there are no detected confounders. Answer A is incorrect because one-way ANOVA is used for testing three or more groups.

Answers B and C are incorrect because chi-square and Fisher exact test are used to test nominal data. Answer D is incorrect because Friedman test is used to test ordinal data.

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6. Which of the following statistical tests would be the most appropriate if the study had evaluated three groups instead of only two? (i.e., bupropion [Zyban] vs. nicotine patches [Nicoderm CQ] vs. nicotine gum [Nicorette])

(A) One-way ANOVA **(B) Chi-square (2)** **(C) Fisher exact test**
(D) Friedman test **(E) Student's t test**

The answer is A

- **Answer A is correct** because one-way ANOVA is used to test parametric data (change in the number of cigarettes smoked daily) when there are three independent groups and no detected confounders are present.
- **Answers B and C are incorrect** because chi-square and Fisher exact test are used to test nominal data.
- **Answer D is incorrect** because Friedman test is used to test ordinal data.
- **Answer E is incorrect** because t test is used for evaluating statistical differences in parametric data when only two groups are being evaluated.

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Biostatistics

7. A study is designed to evaluate the change in blood pressure lowering between metoprolol tartrate (Lopressor®) and metoprolol succinate (Toprol XL®).T e investigators decide to perform a parallel trial in 200 patients. There were significant baseline differences between the groups in diet and exercise. Which of the following statistical tests would be most appropriate?

(A) One-way ANOVA **(B) Chi-square (2)** **(C) Fisher exact test**
(D) ANCOVA **(E) Student's t test**

The answer is D

- **Answer D is correct** because ANCOVA is used to test parametric data (change in BP) when two or more groups are being evaluated and two or more confounders (diet and exercise differences) are detected.
- **Answer A is incorrect** because one-way ANOVA is used when no detected confounders are present.
- **Answers B and C are incorrect** because chi-square and Fisher exact test are used to test nominal data.
- **Answer E is incorrect** because *t* test is used when no detected confounders are present.

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8. The makers of eplerenone (Inspra) want to design a study to compare their medication to the current standard of spironolactone (Aldactone) in the treatment of heart failure. They decide to perform a parallel trial of the two agents in 2000 patients with NYHA classes II to IV heart failure over 2 years. The primary end point is mortality. Which of the following statistical tests would be most appropriate to use?

(A) ANOVA **(B) Fisher exact test** **(C) Chi-square (2)**
(D) Mann-Whitney U test **(E) Student's t test**

The answer is C

- **Answer C is correct** because chi-square is used to detect statistical differences for nominal data (mortality) when there are large numbers of patients in each treatment group.
- **Answers A and E are incorrect** because ANOVA and *t* test are used to test parametric data.
- **Answer B is incorrect** because Fisher exact test is used when there are small numbers of patients in each treatment group (40 patients).
- **Answer D is incorrect** because Mann-Whitney *U* test is used to test ordinal data.

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Biostatistics

9. A retrospective study produces correlation/regression analysis between a high sodium intake (2.4 g/day) and hypertension (HTN) reporting an r =0.45. Which of the following is correct?
(A) 20% of HTN may be explained by high sodium intake.
(B) 20% of HTN is not explained by high sodium intake.
(C) 80% of HTN is explained by high sodium intake.
(D) 55% of HTN is not explained by high sodium intake.
(E) 45% of HTN may be explained by high sodium intake

The answer is A

- **Answer A is correct** because *r* =0.45, *r*-squared (*r*2)_ 0.2 or 20%. Therefore, 20% of one variable (hypertension) may be explained by the other variable (high sodium diet).

- This would mean that 1 _ 0.2 _ 0.8 or 80% of hypertension would not be explained by a high-sodium diet. Therefore, **answers B, C, D, and E are incorrect**.

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10. A study was performed to evaluate a possible correlation between the use of the herbal product Goldenseal and changes in pain relief (based on pain scale scores). Which type of correlation analysis should be used in this trial?
(A) Pearson (B) Spearman (C) Linear (D) Cox

The answer is B

- **Answer B is correct** because pain scale scores are ordinal data, and Spearman is the sample correlation coefficient for ordinal data.
- **Answer A is incorrect** because Pearson is the sample correlation coefficient for linear (parametric) data.
- **Answer C is incorrect** because pain scale is ordinal data, not linear (parametric).
- **Answer D is incorrect** because Cox is a type of regression analysis, not a form of correlation analysis

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11. In biostatistics, what is meant by the mean of a group of values?

A. The calculated value by adding up all the numbers and subtracting by 100
B. The product of all the values divided by the number of values
C. The value that occurs most frequently in the series
D. The average
E. The value in the middle of the list

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Biostatistics

12. In biostatistics, what is meant by the median in a group of values?

A. The relative risk reduction **B. The value in the middle of the list C. The average** **D. The variance squared.**
E. The value that occurs most frequently

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13. In biostatistics, what is meant by the mode in a group of values?
A. The value that corresponds to the 25th percentile
B. The value used to calculate the standard deviation of the mean
C. The value that occurs most frequently
D. When the values are stated numerically in order, it is the value half way down the list.
E. The value that corresponds to the 95th percentile

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14. What is the term used for the inactive or inert substance administered to a patient that serves as a reference to determine the effects of a real drug or other intervention?

A. The relative risk **B. The standard deviation** **C. The null hypothesis**
D. The placebo **E. The desiccant**

Biostatistics

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15. Choose the name of the assertion that a clinical trial is designed to disprove which states there is no difference between two groups (Drug A = Drug B).

A. The assertive hypothesis B. The null hypothesis C. The alternative hypothesis D. Type II error E. The disclaimer

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16. Choose the name of the term used to determine statistical significance in a trial:

A. The Z-value B. The T score C. The p-value
D. The hazard ratio E. The odds ratio

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Biostatistics

16. A clinical trial is conducted on a new drug, LoSod. LoSod is found to reduce serum sodium to 138 mEq/L, with a 95% confidence interval of 136.7 mEq/L to 139.3 mEq/L. What is the correct interpretation of this 95% confidence interval?

A. There is a 95% chance that the interval contains the true population value.

B. When using this drug in a larger population, one can expect that 95% of the patients will have a serum sodium between 136.7 to 139.3 mEq/L.

C. When using this drug in a larger population, one can say with 95% confidence that the serum sodium will be 138 mEq/L.

D. There is a 5% chance that the true population mean is within the stated range.

E. There is a 5% chance that the results of this study are rejected in error.

Biostatistics

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17. **Which of the following statements best describes a type-2 error?**

A. **Risk of a false-positive result**

B. **Alpha error**

C. **Risk of detecting a treatment difference when there is none**

D. **Risk of not detecting a significant difference when there is one**

- **Answer: D.**
- A type-2 or beta error occurs when the null hypothesis is wrongly accepted, i.e. a false-negative.
- For example, in a clinical trial, a type-2 error has occurred when the study fails to detect a significant difference between the two drugs on trial when in fact there is one. This can happen if the sample size is too small.
- Studies therefore have to have adequate power to find a difference if one exists. Formulae are available to help work out the minimal sample size required.

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18. An unpaired t-test is used to compare the mean height in two populations. A random sample is taken from each population and the difference in sample means is 10 cm, with a 95% confidence interval from –2 cm to 22 cm. If the true means in the two populations are 150 cm and 165 cm, which one of the following statements is correct?

a. **The test shows we can be 95% sure there is a difference**
b. **There is no difference in height between the two populations**
c. **A type-1 error has occurred**
d. **A type-2 error has occurred**
e. **A paired t-test should have been used**

Correct answer: D

- The correct test to compare the means of two different populations is an unpaired t-test.
- We have been told the true means and they are different, so **option B is incorrect**.
- The 95% confidence interval for the difference in means includes zero, so the test has not detected a significant difference.
- **The null hypothesis** (no difference in means) is false, but the test has not rejected it; this **is a type-2 error**.
- However, if the null hypothesis was true and the test rejected it, this would be a type-1 error.

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19. A type 1 statistical error in a clinical trial means that:

A : patients were not allocated into groups with an appropriate randomization method
B : the null hypothesis is falsely accepted
C : the null hypothesis is falsely rejected
D : the statistical analysis was incomplete or incorrect
E : the statement of the hypothesis to be tested was incomplete or flawed the null hypothesis is falsely rejected

Answer: C

- **A type 1 error** is formally defined as being where **the null hypothesis** (which is that there is no difference between the groups) was **falsely rejected.**
- In practice this means that the study claims to find a difference that does not really exist,(i.e. the result is a statistical fluke).
- The conventional cut-off for significance is P=0.05, or a 1-in-20 chance.
- Hence if 20 trials were conducted, you would expect to get one that was 'positive' by chance alone.

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Biostatistics

20. A manuscript is submitted to a medical journal regarding a randomized trial in which a new treatment for Clostridium difficile diarrhea is compared with an established treatment. A reviewer states that they are concerned that there might be type 2 statistical error. What does this mean?

A : That the method of statistical analysis used is inappropriate

B : That the study has shown a difference between the treatments that is statistically significant but which is unlikely to be clinically significant

C : That the study claims to find a difference that does not really exist, i.e.. the result is a statistical fluke

D : That the data is skewed (not normally distributed) and analysis should have used non-parametric rather than parametric statistical techniques

E : That the study claims that there is no difference between the treatments, when in reality the trial was just too small to detect a difference.

Correct Answer : E

Comment :

- **The null hypothesis** is always that there is no difference between groups under study.
- **A type 1 error occurs** when 'the null hypothesis is falsely rejected'. In practice this means that the study claims to find a difference that does not really exist, i.e. the result is just a statistical fluke.
- **A type 2 error** occurs when 'the null hypothesis is falsely accepted'.
  This means that it is claimed that there is no difference between two groups, when in reality the study is simply too small to detect a difference. This type of error can be avoided by making explicit power calculations before embarking on any study.
- This will answer the question 'if I am studying an outcome that occurs in (say) 20% of a conventionally treated group and want to show a (say) halving in the rate of this outcome, then how many patients do I need to study?'

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Biostatistics